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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,001

12/13/2006

Matthias Augustin

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EXAMINER

DAVIS, DEBORAH A

ART UNIT

PAPER NUMBER

1655

NOTIFICATION DATE

DELIVERY MODE

06/17/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/588,001	<b>Applicant(s)</b> AUGUSTIN ET AL.	
	<b>Examiner</b> DEBORAH A. DAVIS	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24-47 is/are pending in the application.
- 4a) Of the above claim(s) 29-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12-31-06</u>  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 24-28 in the reply filed on 4-13-09 is acknowledged. The traversal is on the ground(s) that there is at least a special technical feature that links groups I and III together and there would not be a serious burden to examine both groups. This is not found persuasive because although there is a special technical feature that links the groups I and III together, the special technical feature is not a contribution over the prior art because it is anticipated by Barrett et al which discloses coriander oil to treat inflammatory skin conditions. With respect to applicant's argument of burdensome search, restriction is not based on burdensome search alone but includes the criteria of patentably independent or distinct inventions. Further, the search for each invention is not co-extensive particularly with regard to the literature search. If a reference anticipates the invention of one group, it would not necessarily anticipate or even make obvious the other invention.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a microbe-caused disease of at least one skin condition disclosed in the instant claims, does not reasonably provide

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enablement for preventing a microbe-caused disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors regarding undue experimentation have been summarized in *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

- (1) The quantity of experimentation necessary (time and expense);
- (2) The amount of direction or guidance presented;
- (3) The presence or absence of working examples of the invention;
- (4) The nature of the invention;
- (5) The State of the prior art;
- (6) The predictability or unpredictability of the art;
- (7) The breadth of the claims; and
- (8) The relative skill of those in the art

All of the *Wands* factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

**Nature of the invention:** The instantly claimed invention is drawn to a method of treating or preventing a microbe-caused disease of at least one of skin, a mucous membrane and an oral cavity, wherein the method comprises an administration to a subject of an amount of oil of coriander which is effective for treating or preventing the microbe-caused disease

**Breadth of the claims:** The claims were given its broadest and reasonable interpretation that is consistent with applicant's specification.

**Guidance of the Specification and Existence of Working Examples:**

The specification describes a clinical screening study of coriander oil in healing and treating experiments in which it demonstrated efficacy against atypical eczema and nummular eczema. The coriander oil treatment also proved to be effective against tinea diseases as well as Candida interigo. However, the specification does not show any working examples of where the coriander oil prevented any of the microbe-caused diseases of the mucous membrane, oral cavity or the skin. Although the M.P.E.P. does not require working examples, there must be sufficient teaching in the specification to enable one of ordinary skill in the art to use the method as instantly claimed. The specification lacks such teaching and therefore the subject matter for "preventing" such microbe-caused diseases is not enabled. Thus, there has not been provided adequate guidance in the specification for accomplishing this process using the oil of coriander as claimed.

**Amount of Experimentation Necessary:**

The quantity of experimentation necessary to carry out the claimed invention is high, because the skilled artisan could not rely on the instant specification or the prior art to teach a method of administering the oil of coriander to *prevent* a microbe-caused disease. Therefore, in view of the nature of the invention, breadth of the claims and the lack of guidance in the specification as well as the amount of experimentation necessary, the skilled artisan would not be able to practice the invention. Therefore the instant claims are not considered to be fully enabled by the instant specification.

Claim 28 is also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description only sets forth a method for treating a microbe-caused disease by administering coriander oil but not any and all of its derivatives and metabolites thereof. Please note that the phrase “a derivative thereof and a metabolite thereof” envisions any and all potential derivatives of and metabolites of the recited coriander oil. The written description is not commensurate in scope with the claims drawn to any and all derivatives and metabolites of the recited coriander oil. Applicant must convey with reasonable clarity to those skilled in the art that as of the filing date sought, he or she was in possession of any and all derivatives and metabolites of coriander oil. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 111. The invention is for the purposes of the written description inquiry, whatever is now claimed. The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed and was in possession thereof at the time the invention was made.

### ***Claim Objections***

Claim 27 is objected to because of the following informalities: The acronym “MRSP” should be spelled out. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lilley et al UK Publication (GB 2 359 746).

A method of treating a microbe-caused disease of at least one of skin, a mucous membrane and an oral cavity, wherein the method comprises an administration to a subject of an amount of oil of coriander which is effective for treating the microbe-caused disease is apparently claimed.

The cited reference of Lilley et al. beneficially teaches the instant claims by disclosing a one or more of essential oils selected from coriander and others therein for the inhibition of pathogenic bacteria in the oral cavity that define such disorders as gingivitis, periodontal disease, dental caries and particularly disorders related to or caused by the activity of anaerobic bacteria (gram positive bacteria), which the examiner interprets of microbe-caused diseases, as claimed (page 3, lines 5-30, e.g.). The coriander oil can be suitable for administration to humans and animals in the form of pet foods, confectionery, chewing gum, dental floss, mouth rinses, toothpaste and other dental vehicles (page 11, lines 13-15, e.g.), which would be the contact site for the oral cavity. Such oral preparations are applied by contacting the gums by rinsing the oral cavity for about 15-90 seconds, or in the case where lozenges, candy or chewing

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gum are used by sucking or chewing in the oral cavity at least once daily (page 26-31, e.g.).

The reference of Lilley et al. does not expressly teach the step of administering coriander oil to a mammal.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer coriander oil to a mammal based on the beneficial teachings provided by the reference of Lilley. The coriander oil comes in administrable forms for delivery to the oral cavity to treat gingivitis, periodontal disease, and other dental disorders. The adjustment of particular conventional working conditions is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of the evidence to the contrary.

Claim 24-28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lilley et al. in view of Vall III. et al. (US 2004/0009245).

The teachings of Lilley et al have been set forth above but the reference does not teach that coriander oil treats multi-resistant pathogen.



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However, the reference of Vall III, beneficially discloses that concentrated oil vapors from essential oils of coriandrum and other essential oils therein can be used to treat MRSA (paragraphs 0240 and 0409, e.g.).

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lilley and Vall III, based on the beneficial teachings that coriander oil is useful for treating bacterial infections and resistant bacterial infections. The adjustment of particular conventional working conditions is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of the evidence to the contrary.

### ***Conclusion***

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH A. DAVIS whose telephone number is (571)272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deborah A. Davis  
Patent Examiner, AU 1655  
May 2009

/Christopher R. Tate/  
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